Remarks/Arguments

No amendments are made to the claims.

Claim Rejections- 35 USC § 103

THE COMMERCIAL SUCCESS OF THE CLAIMED COMPOSITION RENDERS THE CLAIM NON-OBVIOUS.

"*Graham* and its progeny require the consideration of various secondary indicators of nonobviousness. The secondary indicators listed in *Graham* are: (1) commercial success; (2) long-felt but unsolved needs; and (3) failure of others. "*Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1129 (Fed. Cir. 2000).

In the previous response, Applicants provided evidence of commercial success of an embodiment of the claimed composition in three countries: Brazil, Canada, and Switzerland. Since that declaration was executed, additional commercial success data has been generated. In the interest of full disclosure for the purposes of appeal, and to provide a more compelling argument, Applicants provide herewith a declaration that contains the commercial sales data for that embodiment of the claimed composition in all countries where the product is sold.

This declaration shows that the embodiment of the claimed composition is sold in 28 countries in North America, Europe, and Asia. (See Table 1). This declaration also shows that the combined sales of the embodiment of the claimed composition in these 28 countries has steadily increased since the quarter of first launch (in 3Q 2003) to the second quarter of 2007, while at the same time the sales of a composition containing brimonidine only have remained roughly constant, or increased slightly. Finally, the declaration shows that in

general, sales steadily increase in the individual countries after introduction of the product to the market. Thus, Applicants have shown that the product is commercially successful.

The Office does not appear to dispute that the product is commercially successful, or that the commercially successful product is not the claimed product. However, the Office alleges that "applicant fails to provide the required nexus for nonobviousness based on commercial success." (June 4, 2007 Office Action, p. 5). Applicants recognize that a nexus between the claimed invention and the commercial success is required to establish nonobviousness. However, this nexus is presumed if Applicants show that the commercially successful product is the product or method claimed, and the burden shifts to the Office to rebut this presumption with evidence, not mere argument. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000) ("A nexus between commercial success and the claimed features is required. However, if the marketed product embodies the claimed features, and is coextensive with them, then a nexus is presumed and the burden shifts to the party asserting obviousness to present evidence to rebut the presumed nexus. The presumed nexus cannot be rebutted with mere argument; evidence must be put forth."). *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1397 (Fed. Cir.1988) ("A prima facie case of nexus is generally made out when the patentee shows both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent."). *J.T. Eaton & Co., Inc. v. Atlantic Paste & Glue Co.* 106 F.3d 1563, 1571 (Fed. Cir. 1997) ("When a patentee can demonstrate commercial success, usually shown by significant sales in a relevant market, and that the successful product is the invention disclosed and claimed in the patent, it is presumed that the commercial success is due to the patented invention.").

The claimed method is "[a] method of treating glaucoma or ocular hypertension which comprises topically administering a therapeutically effective

amount of a single composition comprising brimonidine at a concentration of about 0.2% by weight and timolol at a concentration of about 0.5% by weight in a pharmaceutically acceptable carrier thereof, to the affected eye, wherein said composition is administered twice a day." (Claim 1). The commercially successful product is "a topical ophthalmic product...which contains a combination of 0.2% brimonidine and 0.5% timolol in a single composition." (Declaration, item 5). Thus, the method is clearly the intended use of the commercial composition, and as mentioned previously, the Office does not appear to dispute this point. Therefore, Applicants have shown "both that there is commercial success, and that the thing (product or method) that is commercially successful is the invention disclosed and claimed in the patent," and have made "a prima facie case of nexus." Now the burden shifts to the Office to produce evidence to rebut this presumption.

The Office has improperly attempted to shift the burden to the Applicant by alleging that Applicant has "no objective evidences that the alleged commercial success is 'not the result of heavy promotion or advertising, shift in advertising, consumption by purchasers normally tied to applicant or assignee, or other business events extraneous to the merits of the claimed invention.'" (June 4, 2007 Office Action, p. 5). Applicants respectfully request that the Office prove its rebuttal with evidence or remove the rejection.

In light of the declaration submitted herewith and the arguments made herein, Applicants believe that the claim is patentable as it stands. Therefore, Examiner is respectfully requested to allow the claim.

Please charge Deposit Account 01-0885 for any fees related to this response.

Respectfully submitted,

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Enclosures: Rule 132 declaration